

Cook



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP3F4186/FAP3H5661. Fenpropathrin (127901 Danitol) on Tomatoes and Strawberries. Request for conditional registration dated 3/23/95.

MRID No. 43593600, 43593601.
CBTS Nos. 15351, 15352.
Barcode D213684, D213691.

FROM: R. W. Cook, Chemist *RW Cook*
Chemistry Branch I-Tolerance Support
Health Effects Division (7509C)

TO: G. LaRocca, PM 15
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Registration Division (7505C)

and

J. Smith, Acting Section Head
Registration Section
Chemical Coordination Branch
Health Effects Division (7509C)

THRU: E. Zager, Acting Branch Chief
Chemistry Branch I-Tolerance Support
Health Effects Division (7509C)

The petitioner, Valent, requests conditional registration on tomatoes and strawberries for Danitol® 2.4 EC Spray (EPA Reg. No. 59639-35), Danitol® Technical (EPA Reg. No. 59639-76), and by implication, PP3F4186/FAP3H5661. In support of the request, the petitioner has submitted the following information:

Revised Section G for PP3F4186/FAP3H5661, reasonable grounds in support of the petition.

The reasonable grounds include a discussion of dietary exposure and risk assessment, and a discussion of aquatic exposure and mitigation (of interest to EFED, not CBTS/HED).

Section 18 emergency exemptions for 1994-905 were approved under 95-SC-03, 95-TX-07, 94-FL-02, 94-CA-28.

We are aware that a number of Section 18 actions have been approved. Additionally, we have recently recommended for 95-CA-0016. In our previous review of PP3F4186, one of the reasons the proposed use on fresh tomatoes Florida only was determined to be unacceptable was a demonstrated need for fenpropathrin in other states, as evidenced by Section 18 requests. The lack of geographically representative field trial data from such other states was a major deficiency in PP3F4186. A submission currently pending may resolve the deficiency regarding representative field trial data. The petitioner reports that the requested additional plant metabolism study for tomatoes will be submitted in June 1995. A submission of the cotton metabolism study is currently pending.

Market usage forecast (confidential business information) for fenpropathrin use on strawberries and tomatoes.

The market usage forecast is outside the purview of CBTS/HED and the forecast is not reviewed herein. We recommend that the market usage forecast be forwarded to BEAD, for their review.

"Draft" Summary from "A metabolism study with [cyclopropyl-1-¹⁴C]- and [phenyl-U-¹⁴C]-Fenpropathrin on tomato" PTRL No. 486W.

We are unwilling to draw regulatory conclusions from "draft" summary material. We will review the final study when it is submitted according to Agency procedures and includes GLP statement.

"Chronic Dietary Exposure and Risk Assessment for DANITOL: Tolerances and Anticipated Residues in Cotton, Tomatoes, and Strawberries."

We recommend the "Chronic Dietary Exposure and Risk Assessment for DANITOL" be forwarded to SAB for review by Dietary Exposure Analysis Group.

Further, we note the petitioner states that an amended label has been submitted on 2/10/95. We have not received the 2/10/95 amended label, and we should review it if it involves application rate, application frequency, application timing, plant growth stage, preharvest interval or other parameters expected to change the residue profile of fenpropathrin on tomatoes.

Conclusions and Recommendation:

We are unable to recommend for the proposed conditional registration until adequate magnitude of the residue tomato field trial residue data are reviewed, and until the additional plant metabolism study on tomatoes is reviewed.

A review of the magnitude of the residue tomato field trial residue data is currently in progress.

cc:R. W. Cook, RF, Circu, PP3F4186.

7509:CBTS:RWCook:CM#2:Rm804H:4/7/95

TDI:RSQuick:4/10/95:RLoranger:4/10/95:EZager:4/11/95



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